

SUBCHAPTER H—HEALTH ASSESSMENTS AND HEALTH EFFECTS STUDIES OF HAZARDOUS SUBSTANCES RELEASES AND FACILITIES

PART 90—ADMINISTRATIVE FUNCTIONS, PRACTICES, AND PROCEDURES

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AUTHORITY: 42 U.S.C. 9615; 42 U.S.C. 6939a(c).

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§90.1 Purpose and applicability.

The provisions of this part set forth the policies and procedures of the Agency for Toxic Substances and Disease Registry (ATSDR) with respect to its conduct of health assessments and health effects studies under section 104(i) of Comprehensive Environmental Response, Compensation, and Liability Act, as amended by the Superfund Amendments and Reauthorization Act of 1986, and section 3019 of the Resource Conservation and Recovery Act. These provisions apply to ATSDR, as well as its contractors, agents, and those carrying out health assessments and health effects studies pursuant to agreements with ATSDR, such as other Federal agencies and States.

§90.2 Definitions.

Administrator means the Administrator of the Agency for Toxic Sub-

stances and Disease Registry or designee.

ATSDR means the Agency for Toxic Substances and Disease Registry, Public Health Service, U.S. Department of Health and Human Services.

CERCLA means the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (42 U.S.C. 9601 *et seq.*, Pub. L. 96-520), as amended by the Superfund Amendments and Reauthorization Act of 1986 (Pub. L. 99-499).

EPA means the U.S. Environmental Protection Agency.

Facility is defined in 42 U.S.C. 9601(9).

Hazardous substance is defined in 42 U.S.C. 9601(14). In addition, the term includes any pollutant or contaminant which the Administrator determines is appropriate for the purposes of carrying out his or her responsibilities under CERCLA.

Health assessment means the evaluation of data and information on the release of hazardous substances into the environment in order to assess any current or future impact on public health, develop health advisories or other recommendations, and identify studies or actions needed to evaluate and mitigate or prevent human health effects.

Health effects study means research, investigation, or study performed by ATSDR or other parties pursuant to an agreement with ATSDR to evaluate the health effects of exposure to hazardous substances at specific sites. This term includes, but is not limited to, epidemiological studies, exposure and disease registries, and health surveillance programs. This term does not include health assessments.

Owner or operator is defined in 42 U.S.C. 9601(20).

Peer review means review for scientific quality by a panel consisting of no less than three nor more than seven members, who shall be disinterested scientific experts selected by the Administrator of ATSDR on the basis of their reputation for scientific objectivity and the lack of institutional ties

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with any person involved in the conduct of the study or research under review.

Person means an individual, firm, corporation, association, partnership, consortium, joint venture, commercial entity, United States Government, State, municipality, commission, political subdivision of a State, Indian tribe, or any interstate body.

Pollutant or contaminant is defined in 42 U.S.C. 9601(33).

Public health advisory is a statement by ATSDR containing a finding that a release poses a significant risk to human health and recommending measures to be taken to reduce exposure and eliminate or substantially mitigate the significant risk to human health.

Release is defined in 42 U.S.C. 9601(22).

§ 90.3 Procedures for requesting health assessments.

(a) ATSDR will accept requests to perform health assessments for a particular facility or release from any person or group of persons.

(b) All requests to ATSDR to perform health assessments should be addressed to: Assistant Administrator, Agency for Toxic Substances and Disease Registry, 1600 Clifton Road NE., Atlanta, GA 30333.

§ 90.4 Contents of requests for health assessments.

(a) Each request for a health assessment shall contain:

(1) The name, address (including zip code), and telephone number of the requestor;

(2) The organization or group the requestor represents, if any;

(3) The name, location, and description of the facility or release of concern;

(4) A statement providing information that individuals have been exposed to a hazardous substance and that the probable source is a release, or sufficient information to allow the Administrator to make such a finding;

(5) A statement requesting ATSDR to perform a health assessment.

(b) At his or her discretion, consistent with the requirements of CERCLA, the Administrator may decide not to require the preceding infor-

mation be submitted with a request for a health assessment.

(c) Each request for a health assessment should include, where possible:

(1) Any other information pertaining to the facility or release, such as the nature and amount of the hazardous substances of concern or the identities of parties believed to be potentially responsible for the release;

(2) Potential pathways for human exposure, including a description of the media contaminated (e.g. soil, groundwater, air, etc.);

(3) The demographic nature and proximity of the potentially affected human population; and

(4) Other Federal, State, or local governmental agencies which were notified or that investigated the facility or release.

(d) This data collection has been reviewed and approved by OMB in accordance with the Paperwork Reduction Act and assigned the control number 0920–0204.

§ 90.5 Acting on requests.

(a) Upon receipt of a request for a health assessment submitted under this part, ATSDR will determine, in its discretion, whether or not there is a reasonable basis to justify conducting a health assessment. ATSDR will base this determination on, among other factors:

(1) Whether individuals have been exposed to a hazardous substance, for which the probable source of such exposure is a release;

(2) The location, concentration, and toxicity of the hazardous substances;

(3) The potential for further human exposure;

(4) The recommendations of other governmental agencies; and

(5) The ATSDR resources available and other ATSDR priorities, such as its responsibilities to conduct other health assessments and health effects studies.

(b) Where appropriate, ATSDR will request information from other Federal, State, and local governmental agencies, as well as other persons, pertaining to a facility or release which is the subject of a request from the public to ATSDR to conduct a health assessment.

(c) The requestor will be notified in writing of ATSDR's determination that either a health assessment will be performed, a health assessment will not be performed, or that further information concerning the facility or release is required before a decision can be made whether a health assessment will be performed.

(d) If a health assessment is not initiated in response to a request from the public, ATSDR shall provide a written explanation to the requestor of why a health assessment is not appropriate.

§ 90.6 Notification of determination to conduct a health assessment in response to a request from the public.

(a) Following a determination by ATSDR to conduct a health assessment in response to a request from the public, ATSDR shall notify in writing, at a minimum, the following parties of its intent to perform a health assessment:

- (1) The U.S. Environmental Protection Agency;
- (2) The appropriate State government environmental agency;
- (3) The appropriate State and local health departments;
- (4) The requestor;
- (5) The owner or operator of the facility of concern, if their identity is readily available to ATSDR.

In addition, ATSDR will notify, in writing or by telephone, other potentially responsible parties, if their identity is readily available to ATSDR.

(b) At its discretion, ATSDR may notify any other persons which it feels may be affected by the release or have information pertaining to the release.

§ 90.7 Decision to conduct health effects study.

(a) ATSDR may decide, in its discretion, based upon the results of a health assessment or other available information, to conduct a health effects study for a particular site or sites. Such a decision may, in appropriate circumstances, be made prior to the completion of a health assessment for a site or sites. When deciding whether to conduct a health effects study, ATSDR will consider such factors as the results and recommendations of a health assessment for the site or sites and the need for additional information to de-

termine whether individuals have been exposed to hazardous substances, the degree to which such exposure has occurred, and any possible health effects resulting from such exposure.

(b) Should ATSDR decide, in its discretion, to conduct a health effects study, it will notify the parties as specified in § 90.6.

§ 90.8 Conduct of health assessments and health effects studies.

(a) Any interested person or persons may submit data or information to ATSDR for it to consider in its conduct of a health assessment or a health effects study. In performing a health assessment or a health effects study, ATSDR will consider data and information it has independently generated or received from other parties, such as EPA, other Federal agencies, State and local governmental agencies, businesses, citizen organizations, and community groups.

(b) ATSDR may determine it is necessary to conduct a site visit in connection with a health assessment or health effects study. The ATSDR representative may allow the participation of any person in the site visit which he or she, at his or her discretion, determines will aid in the conduct of the health assessment or health effects study.

(c) In the event that the information necessary to perform a health assessment or health effects study is not readily available from other sources, ATSDR may arrange for sampling or additional data gathering at a facility or release for the limited purpose of determining the existence of current or potential health problems.

§ 90.9 Public health advisory.

ATSDR may issue a public health advisory based on the findings of a health assessment, health effects, study, or other ATSDR involvement.

§ 90.10 Notice and comment period.

Following internal review by ATSDR and external peer review of a draft final report of the results of a health effects study, ATSDR will publish a notice that the draft final report is available for public review and comment. At

a minimum, the notice shall be published in at least one newspaper of general distribution in the local where the site is located. The notice shall describe how copies of the draft final report of the health effects study can be obtained and set a reasonable time period for interested persons to submit comments concerning the study. ATSDR may, at its discretion, respond in writing to comments it receives.

§ 90.11 Reporting of results of health assessments and health effects studies.

(a) ATSDR shall provide a report of the results of a health assessment or health effects study to EPA, the appropriate State and local governmental agencies, any person requesting ATSDR to conduct the health assessment, and parties potentially responsible for the release, if their identity is readily available to ATSDR. In addition, such reports shall be available to the general public upon request.

(b) In the event that ATSDR or its representatives conduct medical examinations of individuals in the course of a health effects study and the examination reveals a positive significant medical finding, the individual, and a physician if designated by the individual, will be promptly notified of that significant medical finding by ATSDR.

(c) A summary of the findings of all medical examinations for each individual will be sent by ATSDR to that individual.

(d) All studies and results of research conducted under this part (other than health assessments) shall be reported or adopted only after appropriate peer review.

§ 90.12 Confidentiality of information.

(a) ATSDR shall consider any medical information in individually identifiable form to be confidential information and shall release such information only in accordance with the Privacy Act (5 U.S.C. 552a) or other applicable Federal law.

(b) As provided under section 104(e)(7) of CERCLA, any records, reports, or information obtained from any person under this section shall be available to the public, except that upon a showing

satisfactory to ATSDR by any person that records, reports, or information, or particular part thereof (other than health or safety effects data), to which any officer, employee, or representative of ATSDR has access under this part if made public would divulge information entitled to protection under the Trade Secrets Act (18 U.S.C. 1905), such information or particular portion thereof shall be considered confidential in accordance with the purposes of that section, except that such record, report, document, or information may be disclosed to other officers, employees, or authorized representatives of the United States concerned with carrying out statutorily mandated duties.

(c) In submitting data to ATSDR, a person may designate the data which such person believes is entitled to protection under paragraph (b) of this section and submit such designated data separately from other data submitted under this part. A designation under this paragraph shall be made in writing to the Administrator. However, should ATSDR at any time question such designation, not less than 15 days notice to the person submitting the information shall be given of the intention to remove such trade secret designation from such information. The person may submit a request to the Administrator to reconsider this intention and may provide additional information in support of the trade secret designation. The Administrator shall notify the person in writing of the decision which will become effective no sooner than 15 days after the date of such notice.

§ 90.13 Recordkeeping requirements.

(a) ATSDR shall maintain a record of all health assessments and health effects studies. The Administrator shall, at his or her discretion, determine the contents of the record. At a minimum, the record shall include:

(1) The final ATSDR report of the health assessment or health effects study;

(2) Nonconfidential data and other information upon which that report is based or which was considered by ATSDR;

(3) Nonconfidential data or other information submitted by interested persons pertaining to the health assessment or health effects study;

(4) The protocol for the health effects study;

(5) A list of the individuals responsible for external peer review of the report of a health effects study, their comments, and ATSDR's response to the comments; and

(6) For health effects study, the notice announcing the availability of a draft final report for public review and comment, all comments received in response to the notice, and any responses to the comments by ATSDR.

(b) The record may contain a confidential portion which shall include all information determined to be confidential by the Administrator under this part.

(c) The Administrator may determine other documents are appropriate for inclusion in the record for health assessments or health effects studies.

(d) Predecisional documents, including draft documents, are not documents upon which ATSDR bases its conclusions in health assessments or health effects studies, and are not usually included in the record for health assessments or health effects studies.

(e) The record for ATSDR health assessments and health effects studies will be available for review, upon prior request, at ATSDR headquarters in Atlanta, Georgia.

(f) Nothing in this section is intended to imply that ATSDR's decisions to conduct health assessments or health effects studies, or the reports of health assessments or health effects studies, are subject to judicial review.

§ 90.14 Documentation and cost recovery.

(a) During all phases of ATSDR health assessments and health effects studies, documentation shall be completed and maintained to form the basis for cost recovery, as specified in section 107 of CERCLA.

(b) Where appropriate, the information and reports compiled by ATSDR pertaining to costs shall be forwarded to the appropriate EPA regional office for cost recovery purposes.

PART 93—PUBLIC HEALTH SERVICE POLICIES ON RESEARCH MISCONDUCT

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